

Notice of Allowability

Application No.

10/608,409

Examiner

Deborah Malamud

Applicant(s)

BOILEAU ET AL.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 5/25/06.
2. ☒ The allowed claim(s) is/are 2-19.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|---|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date <u>7/17/06</u> . |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____. |

DETAILED ACTION

1. The examiner acknowledges the amendments received 25 May 2006. Claim 1 is cancelled, and claims 2-19 are pending.

EXAMINER'S AMENDMENT

2. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Ronald Tamura on 13 July 2006.

The application has been amended as follows:

In the claims:

In claim 4, line 10, immediately after "...antiarrhythmic drugs...", --,if any,-- was removed.

In claim 18, line 10, immediately after "...antiarrhythmic drugs...", --,if any,-- was removed.

In claim 19, line 9, immediately after "...antiarrhythmic drugs...", --,if any,-- was removed.

Claim Rejections - 35 USC § 102

3. In view of the amendments to claims 2-4, 6-7, 9-16 and 18-19, and the cancellation of claim 1, the examiner withdraws the rejection under 35 USC 102(e) of claims 1-3, 6-8, 11-13 and 18-19.

Claim Rejections - 35 USC § 103

4. In view of the amendments to claims 2-4, 6-7, 9-16 and 18-19, and the cancellation of claim 1, the examiner withdraws the rejection under 35 USC 103(a) of claims 9 and 14-16.

Allowable Subject Matter

5. Claims 2-19 are allowed.

6. The following is an examiner's statement of reasons for allowance:

Claim 4, as amended by the examiner, is a method comprising administering an antiarrhythmic drug to a patient; receiving patient cardiac signals via an implantable cardiac stimulation device implanted in the patient; analyzing the patient cardiac electrical signals to detect the effects, if any, on the cardiac electrical signals caused by the antiarrhythmic drug; and automatically controlling operation of the implantable cardiac stimulation device based on results of the analysis of the patient cardiac electrical signals; wherein analyzing the patient cardiac electrical signals comprises determining the most likely class of antiarrhythmic drugs taken by the patient. Claim 17 is a method further comprising use with patients receiving Class III antiarrhythmic drugs

wherein controlling operation of the implantable cardiac stimulation device comprises generating a notification signal when RT intervals have returned to a nominal state following patient receipt of the Class III antiarrhythmic drugs. Claim 18 is a system for implementing the method of claims 4, 17 and 19. Claim 19 is a method comprising prescribing at least one specific antiarrhythmic drug to a patient; analyzing the patient cardiac electrical signals to detect the effects, if any, on the cardiac electrical signals caused by the antiarrhythmic drug; and automatically controlling operation of the implantable cardiac stimulation device based on results of the analysis of the patient cardiac electrical signals; wherein analyzing the patient cardiac electrical signals comprises determining the most likely class of antiarrhythmic drugs taken by the patient.

Regarding claims 4, 18 and 19, it is well known in the art of implantable cardiac stimulators to administer drug and electrical therapy simultaneously or consecutively, depending on a patient's needs. Administration of the drug is often dependent on the feedback of the patient's electrocardiographic signal. However, nowhere in the field is there a reference that specifically states, implies or suggests determining the most likely class of antiarrhythmic drugs taken by the patient. Moreover, it would not be obvious to one of ordinary skill in the art to provide such a device and/or method of using the device in this way.

Regarding claim 17, nowhere in the field is there a reference that specifically states, implies or suggests generating a notification signal when RT intervals have returned to a nominal state after use of a class III antiarrhythmic drug. It would not have

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been obvious to one of ordinary skill in the art to provide such a method in a system for treating arrhythmia.

7. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah Malamud whose telephone number is (571) 272-2106. The examiner can normally be reached on Monday-Friday, 8.00am-5.30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Pezzuto can be reached on (571)272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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